OCT 18 2012

510(k) Summary according to 807.92(c)

Date prepared: January 17, 2011
Contact: Jessee Hunt, President
4-Web, Inc.
6170 Research Road,
Suite #219
Frisco, TX 75033
972-841-6126

Trade Name: Cervical Spinal Truss System ® Interbody Fusion Device
Product Class: Class II
Classification: 21 CFR §888.3080 Orthosis, intervertebral fusion
Product Codes: ODP
Panel Code: 87

Indications for Use:
The 4-Web Cervical Spinal Truss System (STS) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. 4-Web Cervical STS implants are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device should be used with supplemental fixation.

Device Description:
The Cervical STS Interbody Fusion Device is a titanium implant that is designed to provide mechanical support to the lumbar spine while biologic fusion takes place. The device is an "open architecture" design consisting of trusses mathematically designed to provide maximum support with the greatest amount of open space throughout the implant for bone growth and fusion. The implant is made from Ti6Al4V alloy.

The device is available in two basic "footprint" sizes, 17mm x 14mm and 14mm x 11mm. These sizes are available in zero and 7 degree lordosis and each of these in 8 heights ranging from 5mm to 12mm in 1mm increments.

Predicate Device(s):
The Cervical STS® Interbody Fusion Device was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. The predicate devices include the BAK/C (P980048), Phantom Plus Cage (K082801), Endoskeleton TC (K100889) and for manufacturing and materials purposes, the 4-Web ALIF STS (K083894, K112316).

Performance Testing:
Preclinical testing performed on the 4-Web Cervical STS® Interbody Fusion Device included static axial compression, static compression shear, static torsion, dynamic axial compression, dynamic compressive shear and dynamic torsion mechanical testing per ASTM F2077. Other mechanical tests included subsidence per ASTM F2267-04 and expulsion testing per an industry accepted methodology.

Conclusion:
4-Web, Inc concludes that the Cervical STS device is the same intended use as the predicate devices. The indications for use are the same and the materials used are also the same as the predicate devices. There are no significant differences in technological characteristics compared to the predicates, and the minor differences that do exist do not raise any new types of safety or efficacy issues. Furthermore, bench testing demonstrates that these differences do not adversely impact device performance. 4-Web concludes that the Cervical STS device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

4-Web, Incorporated
% Silver Pine Consulting, Limited
Mr. Richard Jansen, Pharm. D.
Consultant
13540 Guild Avenue
Apple Valley, Minnesota 55124

OCT 18 2012

Re: K121741
Trade/Device Name: Cervical Spinal Truss System® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 01, 2012
Received: October 02, 2012

Dear Mr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K121741

Indications for Use:

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Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121741